UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EKR THERAPEUTICS, INC.,	:	Honorable Katharine S. Hayden, U.S.D.J
Plaintiff,	:	Civil Action No. 07 CV 1788 (KSH)(PS)
v.	:	
SUN PHARMACEUTICAL INDUSTRIES LTD.,	:	**Electronically Filed**
Defendant.	:	

DEFENDANT SUN PHARMACEUTICAL INDUSTRIES LTD.'S BRIEF IN OPPOSITION TO EKR'S APPLICATION FOR A TEMPORARY RESTRAINING ORDER

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PRELIMINARY STATEMENT

Defendant, Sun Pharmaceutical Industries LTD. respectfully submits this brief in opposition to the application for a preliminary injunction and temporary restraining order filed by Plaintiff, EKR Therapeutics, Inc. As set forth herein, EKR has failed to carry its burden on any of the four elements required to obtain the extraordinary relief of a temporary restraining order.

First, EKR's opening brief fails to demonstrate that Sun's challenge to the validity of the '405 patent at issue "lacks substantial merit." This is not surprising because Sun's invalidity defense in fact has substantial merit. As explained below, Sun's invalidity defense is based primarily on two prior art references owned by Yamanouchi Pharmaceutical Co., Ltd.—the EP '475 application and the EP '705 application, both of which were known by the named inventors before the '405 patent-in-suit was even filed. The EP '705 application reads upon and thereby anticipates the claims at issue, rendering them invalid under 35 U.S.C. § 102(b). A patent is "anticipated" by a prior publication if the invention was described in a printed publication in this or a foreign country more than one year prior to the date of the patent application in the United States. 35 U.S.C. § 102(b). Because the EP '705 patent discloses each and every aspect of the claimed invention, this alone is enough to overcome EKR's request for injunctive relief.

Yet the claims at issue also would have been obvious to a person of ordinary skill in the art based on the combination of the EP '705 application and the EP '475 application, and are therefore also invalid under 35 U.S.C. § 103. EKR has not shown – nor could it show – that either of these defenses "lack substantial merit." EKR's attempted rebuttal of Sun's invalidity defense falls woefully short of the legal standard required for emergency injunctive relief.

Second, EKR has failed to provide any credible evidence to establish that it will suffer immediate irreparable harm that is not compensable by monetary damages if a TRO is not entered. All of EKR's asserted harms are purely economic and thus not irreparable. In fact, the supporting declarations submitted by EKR readily admit that if Sun launches its generic product, EKR may lose a certain quantified, monetary value. EKR's alleged harms are classic examples of harms that are monetarily compensable and do not justify the extraordinary relief of a TRO. The mere fact that a competitor may launch a competing product into the marketplace does not automatically cause the brand company irreparable harm. This is especially true where EKR, through its application, is essentially seeking to extend its ability to charge consumers monopoly prices for its product and keep a generic alternative off the market until the patent expires in November 2009.

As set forth herein, as well as the expert reports of Christopher T. Rhodes, Ph.D. and Dr. Patrick DeLuca, which address Sun's invalidity defense and which have been submitted by EKR in support of its application, EKR has failed to sustain its heavy burden of proof that Sun's invalidity defense lacks substantial merit and that it will suffer immediate irreparable harm. Thus, EKR's application should be denied.

ARGUMENT

I. THE COURT SHOULD DENY EKR's APPLICATION FOR A TEMPORARY RESTRAINING ORDER BECAUSE EKR HAS UNEQUIVOCALLY FAILED TO MEET THE REQUISITE FACTORS

A. Legal Standard – Temporary Restraining Order

EKR has failed to demonstrate that it is entitled to the extraordinary relief of a temporary restraining order ("TRO"). Applications for TROs are governed under the same standard that is applied to applications for preliminary injunctions. *See Biovail Corp. v. U.S. Food & Drug Admin.*, 519 F. Supp. 2d 39, 43 (D.D.C. 2007); *CF Inflight, Ltd. v. Cablecam Sys., Ltd.*, No. 03-

5374, 2004 WL 234372, at *3 (E.D. Pa. Jan. 30, 2004). Like a preliminary injunction, a TRO is "a 'drastic and extraordinary remedy that is not to be routinely granted.'" *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1324-25 (Fed. Cir. 2004) (quoting *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1569 (Fed. Cir. 1993)); *see also E.I. Du Pont de Nemours & Co. v. MacDermid, Inc.*, No. 06-3383, 2008 WL 4952450, at *6 (D.N.J. Nov. 19, 2008) (stating that "[i]njunctive relief is a drastic and extraordinary remedy which should be granted only in limited circumstances," and denying preliminary injunction) (citation omitted). Indeed, "[t]here is no power the exercise of which is more delicate, which requires greater caution, deliberation, and sound discretion, or more dangerous in a doubtful case, than the issuing [of] an injunction." *Falter v. Veterans Admin.*, 632 F. Supp. 196, 201 (D.N.J. 1986).

Here, EKR has failed to establish: (i) a likelihood of success on the merits; (ii) a likelihood of irreparable harm if the TRO is not entered; (iii) a balance of equities tipping in its favor; and (iv) that the TRO is in the public interest. *See Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1375-76 (Fed. Cir. 2009); *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1005 (Fed. Cir. 2009).

Initially, EKR "must establish the existence of *both* of the first two factors to be entitled to a [TRO]." *Altana*, 566 F.3d at 1005 (emphasis added). Therefore, before the Court may even consider a balancing of the equities and the public's interest in this matter, EKR must show a likelihood of success on the merits of Sun's defense that the asserted claims of the '405 patent at issue are invalid and that irreparable harm not compensable by monetary damages will result. Plainly, it has done neither.

Moreover, any attempt to establish these two elements are far outweighed by the fact that a TRO would cause significantly more hardship to Sun than EKR, and that, perhaps worst of all,

the public would be subjected to an even longer period of EKR's unwarranted monopoly prices— in direct contravention of the principal goals of the Hatch-Waxman Act.

II. EKR HAS NOT ESTABLISHED THAT IT IS LIKELY TO SUCCEED ON THE MERITS

EKR has not, and cannot, show a likelihood of success on the merits of Sun's invalidity defense. To satisfy this factor, if an accused infringer (Sun) challenges the validity of the patent, the patentee (EKR) "must persuade the court that, despite the challenge presented to validity, the patentee nevertheless is likely to succeed at trial on the validity issue." *See Titan Tire*, 566 F.3d at 1377. After weighing the evidence for and against validity,

> if the trial court concludes that there is a "substantial question" concerning the validity of the patent, meaning that the alleged infringer has presented an invalidity defense that the patentee has not shown lacks substantial merit, it necessarily follows that the patentee has not succeeded in showing it is likely to succeed at a trial on the merits of the validity issue.

Id. at 1379.

Importantly, "the alleged infringer at the preliminary injunction stage does not need to prove invalidity by the 'clear and convincing' standard that will be imposed at trial on the merits." *Id.* (citing *Amazon.com, Inc. v. BarnesandNoble.com, Inc.*, 239 F.3d 1343, 1358 (Fed. Cir. 2001) ("Validity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial.")). EKR must show, in light of the presumptions and burdens that will be present at any eventual trial on the merits, that Sun's challenges to the validity and enforcement of the '405 patent "lack substantial merit." *See Novartis Corp. v. Teva Pharms. USA, Inc.*, No. 04-4473, 2007 U.S. Dist. LEXIS 42163, at *12 (D.N.J. June 11, 2007). In other words, EKR cannot establish a likelihood of success on the merits if Sun raises a "substantial question" of invalidity or enforceability. *Andrx*, 473 F.3d at 1201.

The Federal Circuit has explained that one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. *Amazon.com, Inc. v. BarnesandNoble.com, Inc.*, 239 F.3d 1343, 1359 (Fed. Cir. 2001). Two pieces of prior art—the EP '705 application and the EP '475 application—and certain representations made to the PTO by the applicant not only establish a "substantial question" of validity—they virtually eliminate any likelihood that EKR can successfully demonstrate at trial the non-obviousness of the '405 patent.

In sum, EKR cannot block Sun's launch of its soon-to-be approved generic product without first establishing that Sun's invalidity defenses lack substantial merit. EKR simply cannot do so.

A. The Asserted Claims Of The '405 Patent Are Invalid

The asserted claims of the '405 patent present a textbook case of anticipation under 35 U.S.C. § 102(b) and obviousness under 35 U.S.C. § 103 and are invalid in view of the prior art. In particular, a person of ordinary skill in the art of formulating drug products would have been motivated to use of a buffer to control the pH of the nicardipine hydrochloride solution, thereby controlling the stability of the product.

(i). Legal Standard of Anticipation

Patent claims may be invalidated where an alleged infringer proves that a prior art reference "anticipates" the invention. 35 U.S.C. § 102(b); *Applied Medical Resources Corp. v. U.S. Surgical Corp.*, 147 F.3d 1374, 1378 (Fed. Cir. 1998); *Medtronic Inc. v. Intermedics, Inc.*, 799 F.2d 734, 741 (Fed. Cir. 1986). A patent is "anticipated" by a prior publication and therefore invalid if the invention was described in a printed publication in this or a foreign country more than one year prior to the date of the patent application in the United States. 35 U.S.C. § 102(b). Invalidity by anticipation is established if each and every element of the

claimed invention appears in a single reference published more than one year before the filing date of the challenged patent. *Verdegaal Brothers Inc v. Union Oil Company of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). The prior art reference need not be identical in wording to the patent at issue. *IMX, Inc. v. LendingTree, LLC*, 405 F. Supp. 2d 479, 489 (D. Del. 2005) (citing *Continental Can Co. USA v. Monsanto, Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). It is sufficient that a person of ordinary skill in the art would have understood each and every claim limitation to have been disclosed inherently in the prior art reference. *Id.* While every element must appear in a single reference, additional references may be used to reveal what it would have meant to those skilled in the art at the time of the invention. *Studiengesellschaft Kohle, m.b.H. v. Dart Indus., Inc.*, 726 F.2d 724, 727 (Fed. Cir. 1984).

(ii). Legal Standard of Obviousness

35 U.S.C. § 103 provides, *inter alia*, that a patent may not be obtained if the differences between the subject matter sought to be patented and the prior art would have been obvious to a person having ordinary skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 3 (1966). The question of whether a claimed invention is unpatentable as obvious under 35 U.S.C. § 103 is a question of law based on underlying findings of fact. *McNeil-PPC, Inc. v. Perrigo Co.*, 337 F.3d 1362, 1368 (Fed. Cir. 2003).

The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* recently significantly changed the landscape where obviousness is at issue, particularly in the context of patents whereby a company seeks to patent a combination of previously known elements. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). The Court flatly stated that "common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions" and that the "combination of familiar elements

according to known methods is *likely to be obvious* when it does no more than yield predictable results." *Id.* at 1731 (emphasis added). The Supreme Court further concluded that a patent claim can be proved obvious merely by showing that the combination of elements was obvious to try:

> The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was obvious to try. When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

Id. at 1741-42. This new standard rejected the rigid application of the prior teaching, suggestion and motivation ("TSM") test employed by the Federal Circuit in favor of a more flexible obviousness standard. *Id.* at 1727. The Supreme Court also discussed the notion that certain improperly granted patents actually halt innovation: "Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility." *Id.* at 1732.[1]

In *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007), the Federal Circuit applied the new standard of *KSR* and held that the inventors "merely used routine research methods to prove what was already believed to be the case." *Id.* at 1364. The Court noted that while the inventors may have advanced the state of the science, their experimentation merely proved conclusively what was strongly suspected before and nothing they did was inventive in nature. *Id.* Citing to *KSR*, the Court held that "[s]cientific confirmation of what was

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[1] The Federal Circuit has recognized that the principals set forth in *KSR* are applicable to pharmaceutical patents. *Takeda Chemical Indus., LTD v. Alphapharm Pty*, 492 F.3d 1350, 1353-54 (Fed. Cir. 2007). This Court has also affirmed the use of *KSR* in chemical compound cases. *See Novartis Pharm. Co. et al. v. Teva Pharma.*, 2007 U.S. Dist. LEXIS 65792 at *14 (Sept. 6, 2007).

already believed to be true may be a valuable contribution, but it does not give rise to a patentable invention." *Id.* at 1363-64. (*citing KSR Int'l* 127 S.Ct. at 1732).

Similarly, in *Novartis Pharm. Co. et al. v. Teva Pharma.,* this Court cited *KSR* for the proposition that "[i]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve a similar device in the same way, using the technique is obvious unless its actual application is beyond his or her skill." No. 05-CV-1887, 2007 U.S. Dist. LEXIS 65792, at *14 (D.N.J. Sept. 6, 2007) (citing *KSR* 127 S.Ct. at 1740). The Court accepted the generic manufacturer's argument that the modification to increase bioavailability of the product at issue was an "'ancient technology' that is exemplified in several prior art references." *Id.* at *23. In fact, the patentee's expert admitted that the modification used is one strategy employed in the field. *Id.* Accordingly, the Court found that the patent in suit was obvious and stated that the "prior art teaching need not be that clearly articulated in terms of specific biologic data". *Id.* at *24.

B. The Asserted Claims are Anticipated and/or Obvious in Light of the Prior Art

(i.) Alleged "Novel" Aspect of the '405 Patent

According to EKR's expert, Dr. Thomas Foster, "the '405 patent discloses a stable pharmaceutical composition for parenteral administration containing nicardipine hydrochloride, a non-chloride isotonicity agent, and a buffering agent in a pharmaceutically acceptable aqueous solution." (Foster Rebuttal Report, ¶ 61). When applying for the '405 patent, EKR acknowledged that the prior art relating to nicardipine hydrochloride was "crowded" as of its filing date in 1989. (*See* '405 patent File History, SPIL037899). However, EKR contends that "the solubility of the nicardipine solutions of the prior art is limited and accompanied by the formation of nicardipine free base which precipitates from solution and forms a yellow sticky

substance adhering to the stirring system and thus requiring prolonged stirring for its removal, assuming it can be dissolved at all." (Foster Rebuttal Report, ¶ 62). EKR purports that the '405 patent solves the solubility problems of the prior art nicardipine solutions by controlling pH throughout manufacturing and processing through the use of a suitable buffer system, such as citric acid and sodium citrate, to maintain the pH in the range of about 3.0-4.5. (*Id.* ¶ 63). EKR has failed to identify any other purported "novel" aspects of the '405 patent. Indeed, according to EKR, the only alleged "novel" aspect of the '405 patent is the use of a buffer to control the pH. As Sun demonstrates herein, the use of a buffer to control pH—as well as the other limitations of Claims 1-4 of the '405 patent—is specifically identified in the prior art.

(ii.) Claims 1-4 of the '405 Patent

Claim 1 of the '405 patent recites a process for producing a stable aqueous pharmaceutical composition containing nicardipine hydrochloride that is suitable for parenteral administration. This process requires the following steps: (1) forming a buffer solution that will maintain the pH of the composition at about 3.0 to 4.5; (2) adding to that buffer solution at least 1 mg/ml nicardipine hydrochloride; and (3) adding an amount of a non-chloride compound effective to render the pharmaceutical composition isotonic.

The specification of the '405 Patent provides an express definition for the term "isotonic", citing *Remington's Pharmaceutical Sciences*:

> The term "isotonic" is used in its conventional sense, as is described in "Remington's Pharmaceutical Sciences," Mack Publishing Company, Easton, Pa., 1985, Chapter 80, page 1455 et seq., especially page 1456, left column, lines 24-33, to mean a fluid corresponding to body fluids including blood and lacrimal fluid, normally having an osmotic pressure which is often described as corresponding to that of a 0.9% solution of sodium chloride.
>
> (Ex. D at col. 3, lines 56-64.)

Claim 1 is stated in the '405 patent as follows:

> 1. In a process for producing a stable pharmaceutical composition containing nicardipine hydrochloride suitable for parenteral administration and useful in the treatment of disease conditions which may be alleviated by the administration of calcium channel blocking agents, which process comprises admixing a therapeutically effective amount of nicardipine hydrochloride and a pharmaceutically acceptable aqueous vehicle comprising at least a major proportion of water, the improvement comprising:
>
> (a) dissolving in a aqueous vehicle consisting essential of water a physiologically and pharmaceutically acceptable buffer in an amount effective to maintain the pH of the pharmaceutical composition at about 3.0 to 4.5, thereby forming a buffered solution; and
>
> (b) adding to said buffered solution at least 1 mg/ml of said therapeutically effective amount of nicardipine hydrochloride, and a physiologically and pharmaceutically acceptable non-chloride compound selected from saccharides, including sorbitol, mannitol, dextrose and glucose, and non-saccharides, including polyethylene glycol and glycerol, in an amount effective to render the pharmaceutical composition isotonic.

Claim 2 is dependent on claim 1 and further requires the step of "terminally sterilizing said pharmaceutical composition by autoclaving."

Claim 3 is an independent claim that is directed at the characteristics of the drug product as opposed to Claim 1 which is directed at the process for manufacturing the drug product. Generally, Claim 3 recites the same limitations as Claim 1. Claim 3 is stated in the '405 patent as follows:

> A pharmaceutical composition suitable for parenteral administration to mammals and useful in the treatment of disease conditions which may be alleviated by the administration of calcium channel blocking agents, which composition comprises:
>
> (a) a physiologically and pharmaceutically acceptable non-chloride compound selected from saccharides, including sorbitol, mannitol, dextrose and glucose, and non-saccharides, including polyethylene glycol and glycerol, in an amount effective to render the pharmaceutical composition isotonic;

> (b) a physiologically and pharmaceutically acceptable buffer, selected from citrate, acetate, phosphate, and lactate buffers, in an amount effective to maintain the pH of the composition at about 3.0 to 4.5;
>
> (c) a pharmaceutically acceptable aqueous vehicle consisting essentially of water; and
>
> (d) at least about 1 mg/ml nicardipine hydrochloride in solution therein.

Claim 4 is dependent on claim 3 and further requires that "the therapeutically effective amount of nicardipine hydrochloride is from about 0.5 mg/ml to about 10 mg/ml of aqueous vehicle and the aqueous vehicle is water (water for injection) alone."

In sum, Claims 1-4 of the '405 patent disclose the following limitations: (1) a buffer solution that will maintain the pH of the composition at about 3.0 to 4.5; (2) a concentration of least 1 mg/ml nicardipine hydrochloride; (3) an amount of a non-chloride compound effective to render the pharmaceutical composition isotonic; (4) terminally sterilizing the pharmaceutical composition by autoclaving; and (5) concentration of nicardipine hydrochloride from about 0.5 mg/ml to about 10 mg/ml of aqueous vehicle and the aqueous vehicle is water for injection alone. Each of these limitations have been disclosed in the prior art.

(iii.) The Yamanouchi Applications

The EP '475 application and the EP '705 application are Sun's primary invalidating prior art references. Yamanouchi Pharmaceutical Co., Ltd. ("Yamanouchi") is the applicant for both. The original assignee of the '405 patent, Syntex—also the employer of the inventors of the '405 patent—acquired Yamanouchi's technology regarding the formulation of parenteral dosage forms that include nicardipine hydrochloride and a non-chloride isotonicity agent in an aqueous vehicle. Syntex, and the inventors of the '405 patent, obtained this information prior to developing the alleged invention described in the '405 patent. (*See* Dey Dep. 451:14-463:24.)

This chronology clearly suggests that the inventors of the '405 patent knew or should have known of the teachings of the EP '705 and EP '475 applications.

(iv.) EP '705 Application

The application that ultimately lead to the EP '705 patent was filed on May 21, 1985, and published to the public on November 27, 1985, available long before the filing date of the '405 patent on February 28, 1989.

Similar to the '405 patent, the EP '705 application describes the formulation and production of a stable isotonic aqueous parenteral dosage form containing nicardipine hydrochloride. In particular, it discloses comprehensive information on the composition and preparation of a nicardipine hydrochloride injection in which (1) the pH is required to be adjusted to a preferred range between 2.5 and 5.5, e.g., 3.5 (*See* EP '705 application, at p.1, lines 22-25; *id.* at p.2, lines 6-8, 18-21); (2) the concentration of nicardipine hydrochloride is at least 1 mg/ml (*id.* at p.2, lines 22-26), (3) tonicity is controlled with the addition of a sufficient amount of non-chloride excipients (such as polyhydric alcohols, sorbitol and mannitol) so that the product is isotonic (*Id.* at p.1, lines 8-21, *id.* at p.2, lines 9-17), and (4) the formulation has been shown to be able to tolerate the thermal stress of autoclaving at temperatures of 100 to 121 °C (*id.* at p.7).

(v.) EP '475 Application

The EP '475 application was first published on July 24, 1985—three and one-half years before the February 28, 1989 priority date of the '405 patent. The EP '475 application describes the use of nicardipine hydrochloride for the manufacture of medicaments for the treatment and prevention of liver damage.

Like the '405 patent, the EP '475 application teaches the preparation of a pharmaceutical composition suitable for parenteral administration that includes the combination of nicardipine hydrochloride, a non-chloride isotonicity agent, and a buffer agent in a pharmaceutically acceptable aqueous vehicle:

> For parenteral administration, such as, for example, intravenous injections, the nicardipine or nicardipine salt is dissolved in a vehicle. Vehicle may be, for example, aqueous vehicle, such as sodium chloride injection, Ringer's injection, ***dextrose injection*** and others, water miscible vehicle, such as ethyl alcohol, polyethylene glycol, or nonaqueous vehicles such a [sic] corn oil, peanut oil or sesame oil. ***Vehicle will be buffered to the proper pH in order to stabilize a solution against chemical degradation and formed in such a way as to control isotonicity of injection.*** Other substances may also be added as antimicrobial or antioxidant agents.
>
> (*See* EP '475 application, at 11, lines 5-17) (emphasis added.)

In addition, the EP '475 application discloses an injectable preparation with a concentration of about 10 mg/ml of nicardipine hydrochloride—.2 g of active ingredient in 20 ml of the aqueous vehicle. (*Id.* at 18, lines 29-36; *id.* at 20, lines 9-12). Moreover, like the '405 patent, the EP '475 cites *Remington's Pharmaceutical Sciences*, which specifically discloses the use of autoclaving for terminal sterilization of parenteral drugs. (*Id.* at 11, lines 30-35.) (*See* SPIL038562-SPIL038563.). *Remington's* further discusses the use of water for injection alone as an aqueous vehicle in parenteral dosage forms. (*See* SPIL038543-SPIL038545.)

In sum, the EP '475 application teaches the composition and preparation of a nicardipine hydrochloride injection in which (1) a buffer agent in a pharmaceutically acceptable aqueous vehicle maintains the pH to prevent chemical degradation; (2) the concentration of nicardipine hydrochloride is greater than 1 mg/ml, and (3) a non-chloride isotonicity agent (such as a dextrose injection) controls the tonicity. Moreover, the EP '475 application relies on the

teachings of *Remington's Pharmaceutical Sciences* that (4) the parenteral dosage form can be terminally sterilized by autoclaving, and (5) that the aqueous vehicle can be water for injection alone.

(vi.) Claims 1-4 of the '405 Patent are Anticipated by the EP '475 Application

The EP '475 application anticipates claims 1 through 4 of the '405 patent. As explained above, Claims 1 and 3 of the '405 patent disclose the following limitations: (1) a buffer solution that will maintain the pH of the composition at about 3.0 to 4.5; (2) a concentration of least 1 mg/ml nicardipine hydrochloride; and (3) an amount of a non-chloride compound effective to render the pharmaceutical composition isotonic. First, Claim 2 of the EP '475 application specifically identifies nicardipine hydrochloride as one of the active ingredients that is within the scope of the claimed invention. (*Id.* at 20, lines 9-12.) Second, Example 6 of the EP '475 application discloses a pharmaceutical composition suitable for parenteral administration whereby the concentration of the active ingredient is about 10 mg/ml, which is a concentration of least 1 mg/ml as required by Claims 1 and 3 of the '405 patent. (*Id.* at 18, lines 29-36.) Third, the specification of the EP '475 application teaches the use of a "dextrose injection" (a non-chloride compound) to render the composition isotonic. In addition, the specification teaches the use of a buffer agent to control the pH and stabilize the solution against chemical degradation. (*Id.* at 11, lines 5-17.) (emphasis added).

While the EP '475 application does not explicitly disclose a pH range at about 3.0 to 4.5, as disclosed in Claims 1 and 3 of the '405 patent, the need to maintain the pH of the composition below 5.2 would have been obvious to the person of skill in the art. With the knowledge of the chemical characteristics of nicardipine, one of skill in the art could have easily calculated the pH that would give the optimum or required solubility. (DeLuca Opening Report ¶ 62).

Furthermore, the EP '475 application cites to *Remington Pharmaceutical Sciences*, which specifically discloses the use of autoclaving for terminal sterilization of parenteral drugs, as set forth in Claim 2 of the '405 patent. (*See* SPIL038562-SPIL038563.) Additionally, it discusses the use of water for injection alone as an aqueous vehicle in parenteral dosage forms, as set forth in Claim 4 of the '405 patent. (*See* SPIL038543-SPIL038545.). Therefore, the EP '475 application specifically teaches each of the limitations set forth in asserted Claims 1-4, rendering them invalid under 35 U.S.C. § 102(b).

(vii.) The Combination Of The EP '475 Application And The EP '705 Application Render Obvious The Limitations Of Claims 1-4 Of The '405 Patent

Alternatively, the combination of the teachings of EP '475 application and the EP '705 application render obvious claims 1-4 of the '405 patent—and EKR nearly admits as much. EKR's expert, Dr. Foster, concedes that the EP '705 application recites all of the elements of the asserted claims except the use of the buffer system to control the pH:

> . . . For example, contrary to the statements in the '705 application, the nicardipine solution made in accordance with the '705 application is not stable during subsequent commercial manufacturing, processing, storage, and administration of the final drug product. Further, the '705 application did not teach the person of ordinary skill that the stability problems were a result of the pH changes that occur during manufacturing, including subsequent formulation and sterilization of the final drug product. Moreover, the '705 application did not teach the person of ordinary skill that pH must be controlled through the use of a buffer system, as opposed to adjustment through the simple addition of acid or alkaline. Finally, nothing in the '705 application taught the person of ordinary skill that nicardipine hydrochloride should be dissolved in a buffered solution first, as opposed to initial dissolution in water.
>
> (Foster Rebuttal Report at ¶ 37.)

Indeed, according to EKR, the only alleged "novel" aspect of the '405 patent is the use of a buffer to control the pH. However, the EP '475 application discloses this "novel" use of a buffer, as well as all other aspects of claims 1 through 4 of the '405 patent.

The fact that the EP '475 application does not explicitly disclose a pH range of about 3.0 to 4.5 is squarely addressed by the EP '705 application. The EP '705 patent provides a process for making the nicardipine hydrochloride injection wherein the polyhydric alcohol and nicardipine hydrochloride are dissolved in water and the pH is adjusted to the preferred pH range. (*Id.* at p.1, line 26 – p.2, line 8; *Id.* at p.2, line 27 – p.3, line 5.) The EP '705 patent further discloses the importance and effect of pH on the stability and solubility of the nicardipine hydrochloride in the formulation, stating that it is necessary to control the pH so that it falls within the range of 2.0 to 6.0 and that a pH between 2.5 to 5.5 is preferred. (*Id.* at p.1, lines 22-25; *id.* at p.2, lines 6-8, 18-21.) The EP '705 application also reports data concerning the chemical stability (potency) of nicardipine hydrochloride at different pH values and even claims a process where the solution pH is 3.5: "A process according to claim 4 or 5 wherein the solution pH is 2.5 to 5, e.g., 3.5." (*See id.* at p.13, lines 25-26 (claim 6).)

Notably, the process in the EP '705 application involves adjusting the pH to the preferred range with the use of an acid or alkali. It does not expressly teach using a buffer solution to control the pH. (*Id.* at p.1, line 26 – p.2, line 8; *Id.* at p.2, line 27 – p.3, line 5.). The EP '475 application does, however, as discussed above. Thus, the combination of the EP '475 application and the EP '705 application render obvious the limitations of Claims 1 through 4 of the '405 patent.

(viii.) Misrepresentations to the PTO

The obviousness of claims 1 through 4 of '405 patent begs the question of how the PTO granted the '405 patent in light of the comprehensive teachings of the Yamanouchi applications. The '405 patent was issued despite a material omission and major misrepresentations to the PTO. *First*, the EP '475 application was never disclosed to the patent examiner. Sun discovered the EP '475 application because prior counsel of record for Plaintiffs, Townsend & Townsend, cited to this application as prior art to EKR's published patent application number 20070244166, which is directed toward a different product, a ready-to-use pre-mixed bolus injection pharmaceutical composition of nicardipine hydrochloride.

Second, while the applicants disclosed the EP '705 application, they provided incorrect data regarding its concentration of the nicardipine hydrochloride solution, which allowed them to falsely distinguish the EP '705 application from the '405 patent. The August 22, 1991 Response and Amendment and the supporting Declaration of inventor Alastair Selkirk contain a number of materially incorrect statements and characterizations, which further render claims 1-4 of the '405 patent invalid. On page 6 of the Response, the applicants characterize the teaching of the EP '705 patent as follows: "[the EP '705 patent] . . . pertains to nicardipine hydrochloride solutions of 0.6 mg/ml, *below* the concentrations required in the present invention." (SPIL037938 (emphasis added).) This statement is incorrect.

The EP '705 patent teaches that concentrations of 0.6 w/v% can be achieved. (*See* EP '705 application, at p.2, lines 22-26.) A solution of 0.6 w/v% equals ***6.0 mg/ml***, not 0.6 mg/ml. Thus, the applicants' statement is in error by a factor of 10. Because of this conversion error, the statement is seriously misleading because, in fact, the EP '705 application allows for concentrations of nicardipine hydrochloride *above* the 1 mg/ml concentrations recited in the

claims of the '405 patent. Without this perceived (tenfold) solubility difference, the applicants would have been entirely unable to distinguish their claimed invention from the invention described in the EP '705 application.

Third, the applicants further mischaracterized the EP '705 patent application to the patent examiner by claiming that "[t]here is also no disclosure in the reference of autoclaving or terminal sterilization." Although literally correct, this statement falsely implies that the EP '705 patentees had not considered the stress which autoclaving would impose on their products. To the contrary, the EP '705 patentees had, in fact, given considerable attention to this matter. The stability data disclosed in the EP '705 application was obtained using temperatures of 100 °C. (212 °F) and 121 °C. (249.8 °F.). (*Id.* at p.7). These temperatures were obviously chosen to replicate autoclaving stress. Pharmaceutical products are not labeled for storage at these temperatures. In fact, this autoclave temperature stress data was obtained based on periods of time well in excess of normal autoclaving times. To conclude that the EP '705 patent application does not disclose autoclaving or terminal sterilization ignores the basic tenets of pharmacology. The applicants' material omission of the EP '475 application and multiple misrepresentations of the EP '705 application demonstrate a breach of the applicant's duty of candor to the PTO and prevented the examiner from properly reviewing the '405 patent application.

III. THERE ARE NO SECONDARY CONSIDERATIONS THAT CAN SAVE THE'405 PATENT IN LIGHT OF SUN'S STRONG SHOWING OF OBVIOUSNESS

When a court reaches the conclusion that asserted claims are *prima facie* obvious, the patentee may attempt to present objective secondary considerations of nonobviousness. *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999). The Supreme Court has recognized only three categories of secondary considerations—commercial success, long felt but

unresolved needs, and failure of others. *Graham v. John Deere Co. of Kansas City*, 383 U.S.1, 17 (1996). Here, EKR has failed to set forth any evidence of secondary considerations to rebut Sun's *prima facie* case of invalidity.

IV. EKR PLAINLY CANNOT SHOW IRREPARABLE HARM

Upon EKR's failure to demonstrate a likelihood of success on the merits, a TRO may not be entered and the Court need not consider EKR's arguments of irreparable harm. *See Titan Tire*, 566 F.3d at 1380; *Altana*, 566 F.3d at 1005. Even if EKR somehow can show a likelihood of success, however, it still cannot establish irreparable harm, which it must do in order to be entitled to a TRO. *See Altana*, 566 F.3d at 1005. If this Court finds that EKR has shown a likelihood of success, it is doubtful that EKR should enjoy a presumption of irreparable harm. Instead, it must present independent proof of such harm. *See eBay Inc. v. MercExchange L.L.C.*, 547 U.S. 388, 393-94 (2006) (rejecting a "general rule," unique to patent disputes, "that a permanent injunction will issue once infringement and validity have been adjudged") (citation omitted); *Girafa.com, Inc. v. Amazon.com, Inc.*, No. 07-787, 2008 WL 5155622, at *1 (D. Del. Dec. 9, 2008 ("Even if Girafa succeeds in demonstrating a likelihood of success on the merits, a presumption of irreparable harm does not follow.") (citing *eBay*, 547 U.S. at 392-94); *Hologic, Inc. v. Senorx, Inc.*, No. 08-133, 2008 WL 1860035, at *15 (N.D. Cal. Apr. 25, 2008) ("Applying a presumption of irreparable harm in the preliminary injunction context would appear to replace equitable considerations with a rule that an injunction, however preliminary, automatically follows a determination that a valid patent has likely been infringed. The court is doubtful that the Supreme Court intended for the presumption to survive for purposes of preliminary injunctions.").[2]

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[2] *See also Voile Mfg. Corp. v. Dandurand*, 551 F. Supp. 2d 1301, 1306 (D. Utah 2008); *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, No. 07-190, 2008

In *Novartis Corporation v. Teva Pharmaceuticals, Inc. et al.*, 2007 WL 1695689 (D.N.J. 2007), this Court held that Novartis, the patentee, was not entitled to a preliminary injunction because, *inter alia*, it had failed to establish that it would suffer any immediate irreparable harm that is not compensable by monetary damages. Novartis argued virtually the same alleged immediate irreparable harm that EKR has alleged here, namely, lost sales revenues, lost market share, irreversible price erosion and loss of business and new product opportunities. The Court rejected all of those as a basis for establishing immediate irreparable harm and held that, while the harm to Novartis may ultimately be substantial, it was not convinced that the potential pecuniary harm was incalculable, especially in light of the fact that Novartis' own witness offered preliminary calculations of the potential pecuniary harm. Id. at * 26-29. The Court, therefore, denied Novartis' application for preliminary injunctive relief.

Here, EKR, just like Novartis, has failed to demonstrate that it will suffer any immediate irreparable harm that is not compensable by monetary damages. EKR's own witness, Richard DeSimone, has provided very detailed information on the alleged monetary harm that will result if Sun launches its generic product. Moreover, these calculations are based on EKR's actual experience with the launch of another generic alternative by Teva Pharmaceuticals, which was ultimately recalled in January 2009. Thus, such economic harms are not the types of irreparable harm that can support a TRO or preliminary injunction. *See Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 683 (Fed. Cir. 1990) (noting that acceptance of the patentee's argument that lost sales alone demonstrate irreparable harm would require a finding of irreparable harm to every patentee); *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996)

WL 114361, at *6 (D. Del. Jan. 8, 2008); *Precision Automation, Inc. v. Tech. Servs., Inc.*, No. 07-707, 2007 WL 4480739, at *3 (D. Or. Dec. 14, 2007); *Tiber Labs., LLC v. Hawthorn Pharms., Inc.*, 527 F. Supp. 2d 1373, 1379-80 (N.D. Ga. 2007); *Sun Optics, Inc. v. FGX Int'l, Inc.*, No. 07-137, 2007 WL 2228569, at *1 (D. Del. Aug. 2, 2007).

(holding that a movant does not establish irreparable harm by arguing loss of revenue and loss of research and development opportunities where money damages are calculable and the defendants have the ability to pay any damages award).

The '405 patent is set to expire in November 2009. Thus, any claimed lost sales, loss of market share, or price erosion allegedly attributable to competition from Sun's generic product can be easily quantified. Moreover, the Federal Circuit has expressly held that "neither the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial"). *Nutrition 21 v. United States*, 930 F.2d 867, 871 (Fed. Cir. 1991).

Additionally, the very same harm that EKR claims it will suffer if Sun is not immediately restrained have been found insufficient to show irreparable harm in circumstances less compelling than those presented here. *See Altana*, 566 F.3d at 1005, 1010-11. In *Altana*, the Federal Circuit affirmed the denial of an injunction while noting that "the district court supported its findings on irreparable harm by stating that the plaintiffs had not shown that the defendants were unable to respond in money damages, that the harms to the [plaintiffs] were exaggerated, and that Altana likely had a business plan in place to deal with the launch of generic competition." *Id.* at 1010. The district court found it hard to believe that the patent holder "had failed to account for potential generic launches," or "that its business would be crushed by the entry of generic versions." *Id.* at 1010, 1011. The Federal Circuit affirmed the district court's skepticism of the credibility of these claims "in light of the expiration of the Hatch-Waxman stay" that would inevitably happen. *Id.* at 1011.

The case at bar is similar to, and even more compelling than, *Altana*. Like *Altana*, EKR has been aware of the fact that the 30 month stay was set to expire on September 5, 2009 since at

least the time the Complaint was filed in 2007. EKR should have been expecting Sun's launch upon expiration of the 30-month stay in early September 2009 and EKR has made strategic decisions to combat this generic competition, as is readily admitted by Mr. DeSimone. In fact, EKR's counsel raised the issue with this Court on July 27, yet did nothing about it until now, after the 30 month stay expired. EKR can certainly not be heard to complain that this came as a complete surprise, or that it was unexpected. Thus, this is not a situation which requires the drastic remedy of a TRO, especially where EKR has been planning for this for some time.

Given the weakness of the '405 patent, and had EKR's dilatory tactics actually failed in the delaying of this case, EKR should have been preparing itself for a possible resolution even earlier. In any event, EKR is undoubtedly already well-prepared for the entry of Sun's product into the marketplace when the '405 patent expires in just a couple of months. Thus, any claims of "irreparable harm" from generic entry, which EKR has anticipated all along, simply ring hollow.

V. SUN WILL SUFFER SIGNIFICANT HARM IF ITS LAUNCH IS FURTHER DELAYED

EKR has exaggerated its own alleged harm and has conveniently ignored the substantial harm to Sun that a TRO would cause. In so doing, EKR has failed to show that the balance of harms tips in its favor. *See Titan Tire*, 566 F.3d at 1375. When evaluating the balance of hardships, "a court must balance the harm that will occur to the moving party from the denial of the preliminary injunction with the harm that the nonmoving party will incur if the injunction is granted." *See Novartis Corp. v. Teva Pharms. USA, Inc.*, No. 04-4473, 2007 WL 1695689, at *28 (D.N.J. June 11, 2007) (citation omitted).

Here, the balance of the hardships clearly falls in Sun's favor. EKR has been in this market for over 17 years and claims to be the only FDA approved IV calcium channel blocker.

EKR also cannot credibly claim any hardship from the entry of a generic alternative, as one other generic manufacturer previously launched a competitive product (although that product was eventually removed from the market for a short time). Thus, once Sun receives FDA approval, Sun is uniquely positioned to compete for a fair share of the market. If Sun's entry is delayed, based on EKR's frivolous TRO application, Sun will then lose its positioning as the only generic alternative on the market between now and the expiration of the patent and will be relegated to competing with other generic products that, contrary to Sun, do not yet have approval from the FDA as a safe and effective alternative to EKR's product. Sun will thus lose a large part of the market share that it is now poised to capture, which loss would be irretrievable.

Also, Sun will face price erosion, just as EKR claims it would, if it must wait to compete with additional generic products. The reality is that the generic price tends to fall faster and further where there are a greater the number of generics that are competing with one another. Thus, if Sun is forced to forego launching its product until the patent expires, the price level and thus profit level of the generic product, approved now as a safe and effective product, is likely to be significantly lower.

Finally, EKR's practice of delaying this case tips the balance of equities even further in Sun's favor. *See Novartis Corp.*, 2007 WL 1695689, at *30 (criticizing the patentee for delaying in filing its motion for a preliminary injunction to after the 30-month stay had expired even though it had been aware of the expiration date for years) As Sun has argued to this Court time and again, EKR's litigation tactic has been the same throughout this litigation: delay, delay, delay. EKR's dilatory tactics, however, have now backfired on it. Had EKR not sought to delay this case at every turn, it perhaps could have obtained a resolution of Sun's invalidity defenses long before Sun's product was on the verge of FDA approval. If EKR is so sure that it would

have prevailed over Sun's invalidity challenge, it could have resolved this case earlier and would not now be fretting over imminent launch of Sun's generic product. It is more likely, however, that EKR is aware that it cannot succeed on the merits, and thus, it chose to do what it has done all along: try to run out the clock. EKR should not be heard to, on the one hand, boast of its likelihood of prevailing over an invalidity challenge, and, on the other hand, decry the imminent launch of a generic competitor that EKR supposedly could have itself prevented by seeking an earlier resolution of this matter. Such calculated and dilatory tactics should not be again rewarded.

VI. THE HARM TO THE PUBLIC FROM ENTRY OF A TRO WOULD BE MASSIVE

EKR cannot show that entry of a TRO would be at all in the public interest. "In exercising their sound discretion, courts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Winter*, 129 S. Ct. at 376-77 (citation omitted). Even if the moving party can show irreparable injury in the absence of an injunction or TRO, any such injury can be outweighed by the public's interest. *Id.* at 376. A court must give serious consideration to the public interest factor. *Id.* at 378-80.

In enacting the Hatch-Waxman Act, "Congress sought to get generic drugs into the hands of patients at reasonable prices—fast." *In re Barr*, 930 F.2d 72, 76 (D.C. Cir. 1991). Here, entering a TRO or preliminary injunction would stand directly in the way of that laudable goal. EKR has already enjoyed a decade of market exclusivity—and has made *billions*—on a patent that should have never been granted. If the TRO is entered, the public will have to continue to endure EKR's monopoly prices, even though a safe and effective, and infinitely more affordable, generic alternative has been approved by the FDA and is prepared for shipment and sale. Even though the patent expires in just a couple of months, the harm to the public is not insignificant,

since EKR has admitted that it reaps millions of dollars per month in *profit* on Cardene I.V. Thus, each additional day the public pays an unwarranted monopoly price amounts to true irreparable harm.

Moreover, the public interest is not served by enforcing a patent likely to be held invalid. *See MacDermid*, 2008 WL 4952450, at *33. Additionally, any public interest EKR might assert is infinitesimal since the '405 patent is set to expire in November 2009. EKR has already exacted enormous and unwarranted profits from the exclusivity of its product. Additionally, EKR is likely preparing, if it has not done so already, to wind down its product as it approaches patent expiration and generic entry. Therefore, EKR has clearly failed to demonstrate that the entry of a TRO, under these circumstances is in the public interest.

VII. ANY TRO ENTERED MUST BE ACCOMPANIED BY A SUFFICIENT BOND

The potential harm to Sun from being wrongly restrained or enjoined is significant. If any TRO or injunction is to be entered, EKR must provide for security to protect Sun, and Sun must have an opportunity to present evidence concerning the amount of a bond.

The Federal Rules mandate and the Court must require that EKR post a bond. Federal Rule of Civil Procedure 65(c) provides: "The court may issue a preliminary injunction or temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." The rule is mandatory. The Third Circuit "has interpreted the bond requirement very strictly." *Hoxworth v. Blinder, Robinson & Co.*, 903 F.2d 186, 210 (3d Cir. 1990); *see also Telamerica Media Inc. v. AMN Television Mktg.*, No. 99-2572, 1999 WL 1244423, at *7 (E.D. Pa. Dec. 21, 1999) ("This requirement must be followed, even when the bond creates a barrier to the granting of an injunction. Such a requirement is necessary to mitigate the risk of economic harm from a preliminary injunction in which the movant ultimately

fails to succeed on the merits.") (citation omitted); *Alexander v. Primerica Holdings, Inc.*, 811 F. Supp. 1025, 1036 (D.N.J. 1993) ("The law in this Circuit is clear—when a risk of financial harm exists for the party to be enjoined, the posting of a security bond is required."); *see also Eisai Co., Ltd. v. Teva Pharms. USA, Inc.*, No. 05-5727, 2008 WL 1722098, at *12 (D.N.J. Mar. 28, 2008) (granting the patentee a preliminary injunction but requiring that it "post security in an amount sufficient to compensate Teva should the injunction later be found to be unjustified").

As stated above, EKR realizes millions of dollars per month in profit each month from Cardene® IV, which is being protected by an invalid patent. As a generic alternative on the market, Sun should enjoy a significant portion of the market and relative exclusivity until patent expiration. With the entry of a TRO, this period is diminished if not completely eviscerated.

Thus, this Court should err on the "high side" in calculating the amount of the security bond. *See Scanvec Amiable Ltd. v. Chang*, No. 02-6950, 2002 WL 32341772, at *3 (E.D. Pa. Nov. 1, 2002); *see also* 13 James Wm. Moore et al., *Moore's Federal Practice* § 65.50[1] (3d ed. 2003) ("An error in setting the bond too high is not serious, because the fee to post bond is usually a fraction of the amount of the bond and because any recovery on the bond would have to be supported by proof of actual damages. On the other hand, an error on the low side may produce irreparable injury, because damages for an erroneous preliminary injunction may not exceed the amount of the bond."). This is especially true in this case, where Sun is poised to capture a share of the market in advance of generic entry upon patent expiration.

Accordingly, pursuant to Rule 65(c) of the Federal Rules of Civil Procedure, the Court should require, as a condition to entry of the TRO (if it finds that entry of a TRO is warranted), that EKR post bond immediately in the amount to be set by the Court to reimburse Sun for any injury if the TRO is later held to be wrongly issued. This amount represents the amount of Sun's

potential lost profits, lost market share, cost of relaunch, re-shipment, and re-distribution, in the event Sun is found to have been wrongfully enjoined or restrained.

CONCLUSION

For the foregoing reasons, the Court should conclude that EKR is not entitled to the relief requested and the request for a temporary restraining order should be denied.

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I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements are willfully false, I am subject to punishment.

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